Supreme Court, U.S.
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No. 01-1492

IN THE

Supreme Court of the United States

MYLAN PHARMACEUTICALS INC.,

Petitioner,

v.

TOMMY G. THOMPSON, SECRETARY OF HEALTH AND HUMAN SERVICES, BERNARD A. SCHWETZ, D.V.M., PH.D., ACTING PRINCIPAL DEPUTY COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION, and U.S. FOOD AND DRUG ADMINISTRATION,
and
BRISTOL-MYERS SQUIBB COMPANY,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

RESPONDENT BRISTOL-MYERS SQUIBB COMPANY'S BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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COUNTERSTATEMENT OF THE QUESTIONS PRESENTED

1. Whether a private litigant may bring an action to enforce the Federal Food, Drug and Cosmetic Act ("FFDCA"), despite the fact that there is no private right of action under that statute?

2. Whether a private litigant may bring an action to enforce the FFDCA by characterizing its claim as one for declaratory judgment with respect to a non-existent patent defense?

STATEMENT PURSUANT TO SUPREME COURT RULE 29.6

This is to certify that Respondent Bristol-Myers Squibb Company has no corporate parents and that no publicly traded company owns 10% or more of its stock.

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Respondent Bristol-Myers Squibb Company ("BMS") requests that the Court deny the petition for a writ of *certiorari* seeking review of the opinion of the Court of Appeals for the Federal Circuit reported at 268 F.3d 1323.

COUNTERSTATEMENT OF THE CASE

This case was at its inception, and remains today, an attempt by a private litigant to enforce the Federal Food, Drug and Cosmetic Act ("FFDCA"). Mylan's complaint sought a determination that U.S. Patent No. 6,150,365 (the "'365 patent") was listed in the Food and Drug Administration's ("FDA's") publication entitled *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book", in violation of provisions of the FFDCA governing such listings, and requested an order compelling the delisting of the patent. *See Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1328 (Fed. Cir. 2001). The Federal Circuit found that Mylan's "entire cause of action rests on proving that Bristol improperly listed the '365 patent because it does not comply with the requirements of 21 U.S.C. § 355(b)(1) (Pet. App. 84a).[1] In substance, Mylan's claim is analogous to those barred in the long line of cases precluding private rights of action under the FFDCA." *Id.* at 1332. The court below therefore concluded that Mylan had no cause of action. The petition before this Court seeks review of that decision despite the fact that no court has ever found a private right to enforce the FFDCA, and despite the fact that petitioner conceded before the Federal Circuit that such a claim was not cognizable. *Id.* at 1330.

Since it clearly has no action under the FFDCA, petitioner seeks here, as it did in the Federal Circuit, to reach its desired

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[1] References to a number preceded by "RA" are to respondent's Appendix annexed hereto. References to a number preceded by "Pat. A" are to respondent's Patent Appendix, submitted under a separate cover pursuant to Sup. Ct. R. 33.1(c). References to a number preceded by "Pet. App." are to petitioner's Appendix.

result through the "back door", by arguing that its cause of action should be permitted under the Declaratory Judgment Act ("DJA") because improper listing of a patent in the Orange Book should be a defense to patent infringement. As the Federal Circuit observed, "'[a]n attempt, by ingenious pleading, to escape one principle of law by making it appear that another not truly appropriate rule is applicable appears to have been attempted.'" *Id.* at 1332-33 (*quoting Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993)).

Petitioner's argument is that its case should be construed as a suit for declaratory judgment of noninfringement. But this case has never been an action for a judgment of noninfringement. Mylan's complaint does not seek such a declaration, and Mylan's counsel emphatically disclaimed seeking that in his argument to the district court, stating: "There is no issue here of infringement." (RA 2, *see also* RA 3.) Rather, counsel explained, the issue raised was whether the '365 patent satisfied the requirements of 21 U.S.C. § 355(c)(2) (Pet. App. 90a). *Id.* In fact, Mylan sought to litigate the issue of infringement in an entirely separate declaratory judgment action, which it commenced in a different court (the Northern District of West Virginia). *See* Complaint for Declaratory Judgment, *Mylan Pharms. Inc. v. Bristol-Myers Squibb Co.* (N.D. W. Va. Nov. 28, 2000) (Civ. Act. No. 1:00CV205). (RA 4-11.)

Moreover, even if petitioner's action could be recast as one for a declaration of noninfringement, the purported basis for that claim cannot stand. The allegedly "improper" listing of a patent in the Orange Book is not a defense to infringement. There is no provision in any statute or case for such a defense, nor is there any justification for creating one. In essence, petitioner contends that, by enacting the Hatch-Waxman Amendments, Congress *sub silentio* both created an infringement defense of "improper patent listing" and overturned the longstanding rule that only the government may bring actions to enforce the FFDCA. Mylan's position is

entirely untenable and provides no basis for a grant of the writ of *certiorari*.

A. Factual Background

1. BMS, Mylan and Buspirone

BMS markets and sells BuSpar®, for which BMS holds the new drug application ("NDA"). (RA 12.) BuSpar® is an anti-anxiety medication used in the management of anxiety disorders and the short-term relief of the symptoms of anxiety. (RA 16.) The active ingredient in BuSpar® is buspirone hydrochloride ("buspirone"). (RA 14.)

Mylan is one of the nation's largest generic drug manufacturers. (RA 33.) Mylan has submitted to the FDA two abbreviated new drug applications ("ANDAs"): ANDA No. 75-272 to market and sell 5, 10 and 15 mg generic buspirone products (RA 35); and ANDA No. 76-008 to market and sell 30 mg generic buspirone products. (RA 40.)

2. The '365 Patent

On November 21, 2000, the United States Patent & Trademark Office (the "PTO") issued the '365 patent, which is owned by BMS. (Pat. A 1-14.) The '365 patent discloses a process for alleviating anxiety by systemic administration of a metabolite of buspirone, known as BMY 28674. The sole claim in the '365 patent provides:

> "A process for ameliorating an undesirable anxiety state in a mammal comprising systemic administration to the mammal of an effective but non-toxic anxiolytic dose of [BMY 28674] or a pharmaceutically acceptable acid addition salt or hydrate thereof." (Pat. A 14 at Col. 16, lines 27-32 (emphasis added).)

The patent specification expressly defines two ways to achieve "systemic administration" of BMY 28674: (1) direct administration of BMY 28674 (Pat. A 11 at Col. 10, lines 19-47), and (2) oral administration of a precursor or

prodrug form of BMY 28674 such as buspirone. (Pat. A 12 at Col. 11, line 64 to Col. 13, line 45.)

3. The Listing of the '365 Patent in the Orange Book

BMS submitted information about the '365 patent to the FDA, as required by law, for listing in the Orange Book. (RA 42-43.) Generic drug makers seeking permission to sell generic versions of BuSpar®, including Mylan, challenged the Orange Book listing by submitting objections to the FDA, asserting that the '365 patent only claimed the use of the metabolite, BMY 28674, not the prodrug buspirone. The FDA then asked BMS to submit further information in support of its Orange Book listing. In response to the FDA's request, BMS's FDA counsel submitted a letter to the FDA containing additional information and legal analysis, as well as an additional declaration stating what the patent claim and specification explicitly provide:

> "United States patent 6,150,365 . . . contains a claim for the approved uses of buspirone hydrochloride. The sole claim of United States patent 6,150,365 claims a method for ameliorating an undesirable anxiety state comprising the direct administration of 6-hydroxy-buspirone or oral administration of a prodrug of 6-hydroxy-buspirone such as buspirone hydrochloride to provide an effective but non-toxic anxiolytic dose of 6-hydroxy-buspirone." (RA 48.)

The FDA thereafter deemed the '365 patent listed in the Orange Book as of November 21, 2000. (RA 50.)

B. The FFDCA's Patent Provisions

Filing an ANDA seeking approval of a generic version of a drug prior to the expiration of a patent listed in the Orange Book is deemed an act of infringement. 35 U.S.C. § 271(e)(2)(A). A generic manufacturer filing such an ANDA must file a "paragraph IV" certification with respect to that patent, and provide notice of such certification to the NDA and patent holders. *See* 21 U.S.C. §§ 355(j)(2)(A)(vii) (Pet. App.

108a), (j)(2)(B)(ii) (Pet. App. 110a); 21 C.F.R. § 314.94(a)(12)(i)(A). In a paragraph IV certification, the ANDA applicant certifies that it does not infringe the listed patent and/or that the patent is invalid. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (Pet. App. 109a); 21 C.F.R. § 314.94(a)(12)(i)(A)(4). Here, because Mylan sought approval to market its generic buspirone products before the expiration of the '365 patent, it was required to file a paragraph IV certification in connection with its ANDAs and to give BMS notice of that certification.

When a patentee (such as BMS) receives notice of a paragraph IV certification, and the patentee then sues the generic applicant for patent infringement before the expiration of 45 days from receipt of such notice, the FDA is barred from granting final approval to the generic applicant's ANDA until the earlier of the expiration of 30 months (from the date the notice of certification is received) or a court decision invalidating the patent or finding it not to be infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I) (Pet. App. 118a).

C. Proceedings Below: Mylan's End-Run Strategy

Rather than submit the required paragraph IV certification, Mylan filed a lawsuit against BMS on November 28, 2000, in the United States District Court for the Northern District of West Virginia, seeking a declaration of non-infringement and invalidity with respect to the '365 patent. (RA 4-11.) That suit was (and is) barred by the FFDCA, because it was filed before the expiration of 45 days from receipt by BMS of a notice of paragraph IV certification (and because it was filed in an improper venue). *See* 21 U.S.C. § 355(j)(5)(B)(iii) (Pet. App. 117a).

On November 30, 2000, Mylan commenced this lawsuit in the United States District Court for the District of Columbia against both BMS and the FDA (RA 54), despite the fact that Mylan's claim against BMS is also plainly barred by the FFDCA (*see* 21 U.S.C. § 355(j)(5)(B)(iii) (Pet. App. 117a)). Without

a cognizable claim for relief, Mylan challenged (1) BMS's submission to the FDA of information relating to the '365 patent; (2) the FDA's decision to publish BMS's submission in the Orange Book; and (3) the FDA's decision to withhold approval of Mylan's ANDA 75-272 (not its ANDA 76-008) prior to the expiration of the waiting period imposed by Congress. (RA 61.)

After commencing this lawsuit, Mylan gave BMS notice that it had submitted a paragraph IV certification as to ANDA No. 76-008 (30 mg buspirone).[2] (RA 39-41.) Mylan never gave BMS notice of a paragraph IV certification with respect to ANDA No. 75-272 (5, 10 and 15 mg buspirone).

In an Order dated March 13, 2001, the district court in this case entered a preliminary injunction directing BMS to "delist" the '365 patent from the Orange Book and directing the FDA to grant final approval of Mylan's ANDA No. 75-272. (RA 63-64.) Mylan promptly commenced marketing its generic buspirone product and continues to market that product. (RA 65.) The Federal Circuit reversed the district court's decision, finding that Mylan had no right of action under the FFDCA and that alleging improper listing of a patent in the Orange Book is not a defense to a claim of patent infringement.

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[2] Within the 45-day period provided by the FFDCA, BMS commenced suit against Mylan Pharmaceuticals, Inc., Mylan Laboratories, Inc. and Mylan Technologies, Inc. in the Southern District of New York for infringement of the '365 patent. In an opinion dated February 14, 2002, the court found that the '365 patent does not claim the use of buspirone, that Mylan did not infringe the '365 patent, and that if the patent were infringed, the patent would be invalid. *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 340, 363 (S.D.N.Y. 2002). BMS has filed a notice of appeal to the Federal Circuit. Notice of Appeal, *In re Buspirone Patent Litig.*, (S.D.N.Y. Apr. 24, 2002) (MDL No. 1410 (JGK)).

REASONS FOR DENYING THE WRIT

I. A CLAIM TO "DELIST" A PATENT FROM THE FDA'S ORANGE BOOK IS NOT COGNIZABLE UNDER THE FFDCA.

The court below carefully considered Mylan's purported claim, and was "forced to conclude that Mylan's action here against Bristol is in essence an attempt to assert a private right of action for 'delisting' under the FFDCA". *Mylan*, 268 F.3d at 1332. The court then held that there was no private right of action available:

> "We see nothing in the Hatch-Waxman Amendments to alter the statement in section 337(a) of the FFDCA that 'all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States'." *Id.*

To begin, it should be noted that Mylan waived any argument that it has a cause of action under the FFDCA. In the briefing before the Federal Circuit, BMS argued that there is no private right of action under the FFDCA. In response, Mylan made no argument in support of the existence of a private right of action, but rather, as noted above, represented that it was not seeking to enforce the FFDCA. (RA 67.) After Mylan failed to offer any support for the existence of a private right of action either in its brief or at oral argument, the Federal Circuit correctly found that Mylan had conceded the point. *See Mylan*, 268 F.3d at 1330.

Indeed, Mylan does not appear to argue in its petition that any private right of action is permitted under the FFDCA. Instead, Mylan limits itself to arguing that the FFDCA does not bar its action because the action is not "really" one to enforce the FFDCA. This contention must fail. The entire point of Mylan's suit is to seek a determination that the '365 patent was listed in the Orange Book in violation of the requirements of the FFDCA and should be removed. Both the district court and the

Federal Circuit expressly found that was the gravamen of Mylan's action. *Id.* at 1332; 139 F. Supp. 2d 1, 12 (D.D.C. 2001). There could not be a clearer example of a private litigant attempting to enforce the FFDCA.

The Federal Circuit determined that such an action is not permitted by the statute, and there is no doubt that finding was correct. Every federal court that has ever considered the issue has held that the FFDCA does not permit a private right of action to enforce or restrain violations of its provisions and accompanying regulations. *See, e.g., In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 788 (3d Cir. 1999); *Eli Lilly & Co. v. Roussel Corp.*, 23 F. Supp. 2d 460, 476 (D.N.J. 1998).[3]

Mylan does not cite a single authority to support the existence or creation of a new cause of action to delist a patent from the Orange Book. Instead, it argues that Section 337(a) does not prohibit all private actions, but rather is limited to safety and health aspects of the FFDCA. Even this narrow point cannot stand. Mylan's attempt to read Section 337(a) to apply only to actions to enforce the safety and health aspects of the FFDCA places an unnatural construction on the plain language of the statute. When Congress enacted the listing provisions of 21 U.S.C. § 355, Pub. L. No. 98-417, § 102, 98 Stat. 1585, 1592-93 (1984) (Pet. App. 84a), it was settled law that Section 337(a) precluded private actions to enforce any obligation under the FFDCA. *See, e.g., Fiedler v. Clark*, 714 F.2d 77, 79 (9th Cir. 1983); *Pac. Trading Co. v. Wilson & Co., Inc.*, 547 F.2d 367, 370 (7th Cir. 1976); *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455, 460 (4th Cir. 1960). "Congress is

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[3] *See also Minnesota Mining and Mfg. Co. v. Alphapharm Pty. Ltd.*, Nos. 01-1369, 01-1370, 2002 WL 826930, at *1 (Fed. Cir. May 1, 2002); *PDK Labs., Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997); *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993); *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990); *Rodriguez v. SK & F Co.*, 833 F.2d 8, 9 (1st Cir. 1987).

presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change." *Lorillard v. Pons*, 434 U.S. 575, 580 (1978). Yet, Congress indisputably did not provide for a right of action to enforce any of the new provisions contained in the Hatch-Waxman Amendments. *See* 21 U.S.C. § 355 (Pet. App. 84a); *In re Cardizem CD Antitrust Litig.*, 90 F. Supp. 2d 819, 837 (E.D. Mich. 1999); *Aetna U.S. Healthcare, Inc. v. Hoechst Aktiengesellshaft*, 54 F. Supp. 2d 1042, 1054-55 (D. Kan. 1999). Moreover, two federal courts have expressly rejected the sort of limited construction of Section 337(a) proposed by Mylan. *See Nat'l Women's Health Network, Inc. v. A.H. Robins Co., Inc.*, 545 F. Supp. 1177, 1179 (D. Mass. 1982); *Bailey v. Johnson*, 48 F.3d 965, 967-68 (6th Cir. 1995).

Mylan also argues that the court below mistakenly relied on this Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Again, Mylan is mistaken. The Federal Circuit only cited *Buckman* as consistent with and generally supportive of the decision below, which it certainly is. In *Buckman*, the Court stated that "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions [of the FFDCA]." *Id.* at 349 n.4. Nothing in *Buckman* can be construed to suggest that the well-settled law that Section 337(a) bars private rights of action under the FFDCA was modified by passage of the Hatch-Waxman Act.

The court below correctly found that there is no private right of action to enforce the FFDCA. Mylan has identified no basis for review of that holding, let alone its reversal.

II. MYLAN FAILED TO STATE A CLAIM UNDER THE DJA BECAUSE THERE IS NO DEFENSE OF "IMPROPER LISTING".

Finding itself barred from directly enforcing the FFDCA, Mylan seeks to reach the same result indirectly, by repackaging its action as a purported claim for declaratory relief with respect to a hitherto unknown defense to patent infringement. Mylan's contention is untenable.

First, renaming a claim does not change its nature. Whatever it may be called, Mylan's action seeks the same result: a finding that the '365 patent was listed "improperly" in violation of the FFDCA and an order removing the patent from the Orange Book. That is an action to enforce the FFDCA, which no private litigant is permitted to bring.

Second, in attempting to save its cause of action by reclassifying it, Mylan is, in essence, taking the position that its action is one for declaratory judgment of noninfringement by reason of an "improper listing". But this has never been an infringement case. Mylan never sought a declaration of noninfringement in this action. Neither its original nor its first amended complaint seek such relief. *See* Complaint, *Mylan Pharms. Inc. v. Thompson* (D.D.C. Nov. 30, 2000) (Civ. Act. No. 1:00 CV 02876); First Amended Complaint, *Mylan Pharms. Inc. v. Thompson* (D.D.C. Dec. 7, 2000) (Civ. Act. No. 1:00 CV 02876). Its counsel expressly represented below that infringement was not an issue in this case. (RA 2-3.) Mylan sought to litigate the issue of infringement in an entirely separate declaratory judgment action filed in a different court, the Northern District of West Virginia. *See* Complaint for Declaratory Judgment, *Mylan Pharms. Inc. v. Bristol-Myers Squibb Co.* (N.D. W. Va. Nov. 28, 2000) (Civ. Act. No. 1:00CV205).

Third, and in any event, the "defense" Mylan purports to assert does not exist. Mylan describes the Orange Book listing of a patent as "the predicate act for establishing infringement"

under Section 271(e)(2), and argues that if the listing is not "proper", there is no infringement. This leap of logic is untenable. Section 271(e)(2) does not refer to Orange Book listings, let alone "proper" listings. Rather, it defines infringement as the submission of an ANDA "if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . the use of which is claimed in a patent before the expiration of such patent". 35 U.S.C. § 271(e)(2)(B). The procedure of Orange Book listings and paragraph IV certifications provides notifications (to the FDA, ANDA filer and patent owner) that enable the regulatory gating system to function. To be sure, Section 271(e)(2) and the other parts of Hatch-Waxman operate together in a complementary way. However, nothing in any of the applicable statutes makes a "proper" Orange Book listing an element of infringement.[4] Nor is there anything in the statutes that makes an "improper" listing a defense. Given the highly technical nature of this area of law, and the "artificial" nature of infringement under Section 271(e)(2), it is to be expected that any defenses specific to this cause of action would be set forth in statutory form. The fact that there is no statutory provision for a defense of "wrongful listing" demonstrates conclusively that there is no such defense.[5]

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[4] Indeed, the Federal Circuit has held that the infringement inquiry under Section 271(e)(2) is similar to any other infringement scenario. *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249 (Fed. Cir. 2000) ("the focus of the infringement inquiry under 35 U.S.C. § 271(e)(2) is on the product that will be sold after the FDA's approval of the ANDA").

[5] Mylan relies heavily on this Court's discussion in *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990), of the Hatch-Waxman system and, in particular, 35 U.S.C. § 271(e)(2). That reliance is misplaced. *Eli Lilly* merely discussed the Hatch-Waxman framework in the context of an exercise in statutory construction. It did not determine whether an action may be brought for delisting, or whether "improper listing" could be a defense to a claim of infringement. Nor did it suggest the answer to either of those questions.

Finally, if, as Mylan contends, this action is the declaratory judgment equivalent of a patent infringement case under 35 U.S.C. § 271(e)(2)(A), it is barred by 21 U.S.C. § 355(j)(5)(B)(iii) (Pet. App. 117a). Under the FFDCA, an ANDA holder cannot commence a declaratory judgment action with respect to a listed patent before the expiration of 45 days from the date the patent owner receives notice of a paragraph IV certification. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(III) (Pet. App. 118a). The FFDCA expressly provides:

> "Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of Title 28, for a declaratory judgment with respect to the patent." *Id.*

The statute's language could not be clearer or more broadly worded. It does *not* say that some actions may be brought. It states that "no action" for a declaratory judgment "with respect to the patent" may be brought. If, as Mylan contends, the present action seeks a declaration on a defense to infringement, then it is an action for a declaratory judgment with respect to the '365 patent.

It is undisputed that Mylan brought this case before the expiration of 45 days from the date on which BMS (as the patent owner) received notice of a paragraph IV certification from Mylan (relating to ANDA No. 76-008). This action was thus barred. Any other conclusion would effectively abrogate the FFDCA's prohibition of preemptive declaratory judgment actions.[6]

Mylan's effort to disguise its FFDCA claim as a patent law claim is unavailing and provides no basis for review of the decision below.

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[6] Where, as here, the plain meaning of a statutory provision is clear and unambiguous, courts must give it effect. *See, e.g., Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 571 (1982).

III. THE DECISION BELOW IS CONSISTENT WITH THE POLICIES EMBODIED IN THE HATCH-WAXMAN AMENDMENTS.

In a tacit admission that there is no legal basis for its position, Mylan begins its petition with a policy argument -- that the exclusive policy of the Hatch-Waxman Amendments was to promote the availability of cheap, generic drugs, and that the decision below will thwart that policy. Because the premise of Mylan's argument is incorrect, its contention does not withstand analysis.

There were, in fact, two counterbalanced policies behind the Hatch-Waxman Amendments. One goal was to make it easier for generic drugs to reach the marketplace after applicable patent rights expired. Another goal was to ensure that innovator pharmaceutical companies would have enhanced protection of their intellectual property. As the Federal Circuit observed in this case,

> "[t]hese provisions of the Hatch-Waxman Amendments 'emerged from Congress' efforts to balance two conflicting policy objectives: to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.' *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir.1990) (Edwards, J., dissenting on other grounds)." *Mylan*, 268 F.3d at 1326.

Indeed, Mylan itself acknowledges the dual purposes of the Hatch-Waxman Amendments in a later section of its petition. (Pet. at 17-18.)

The decision below comports fully with these twin policies. The Hatch-Waxman Amendments created a system for resolving patent disputes between innovator pharmaceutical companies and generic drug manufacturers. That system is a carefully balanced compromise that, on the one hand, provides

a generic drug maker a simple route to approval by allowing it to "piggyback" on the pioneer's clinical research, and, on the other hand, requires that the generic's ANDA will not be approved until the pioneer has had a full and fair opportunity to have its patent rights adjudicated in properly instituted patent infringement litigation. The decision below preserves this balance by ensuring that generic drug makers must follow the procedure laid down by Congress for resolving patent infringement disputes in the pharmaceuticals industry.

At bottom Mylan contends, in effect, that there must be a private right of action under the FFDCA because the FDA views its role in listing patents as ministerial, and if there is not a private right of action then there will be no one to enforce the FFDCA. That contention is a red herring. The statute commits the power of enforcement to the FDA. The FDA has decided how it will exercise that power and, accordingly, has created a procedure for dealing with Orange Book listings. This includes a procedure for challenges to those listings, which it followed here. This does not suggest that the private right of action Mylan seeks does or should exist. The entire system enacted by Congress in the Hatch-Waxman Amendments and implemented by the FDA is designed to channel private patent disputes into properly instituted patent infringement suits, such as the one brought by BMS in the Southern District of New York.[7] Mylan here seeks an exemption from the statutory system. No such

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[7] While BMS disagrees with the decision of noninfringement and invalidity rendered in the Southern District of New York and, as stated above, has noticed its appeal, BMS contends that the decision demonstrates that there is no deficiency in the Hatch-Waxman procedure as it has been construed by the Federal Circuit. BMS listed a patent in the Orange Book, Mylan filed a paragraph IV certification with respect to one ANDA, BMS then brought suit for infringement and a timely decision was rendered by the district court. This shows that, contrary to Mylan's contention in its petition, the Hatch-Waxman system works and generic drug makers can get timely resolution of patent disputes.

"out" has been recognized, no such out is needed, and no such out should be implied.

IV. THIS CASE DOES NOT MERIT FURTHER EXPENDITURE OF JUDICIAL RESOURCES.

While not technically moot, Mylan's request for relief in this case does not merit further expenditure of judicial resources. As previously noted, the patent at issue was delisted from the Orange Book pursuant to the district court's preliminary injunction and BMS has taken no action to relist the patent. Further, as also has been noted, the Southern District of New York has found the patent at issue not infringed by Mylan or, in the alternative, invalid. Accordingly, a number of hurdles would have to be surmounted before the question of the listability of the patent and any impact such a listing would have on Mylan's marketing activities could even arise again:

- The decision of the Southern District of New York would have to be reversed by the Federal Circuit;
- BMS would have to resubmit the patent to the FDA for listing in the Orange Book;
- The FDA would have to agree to list the patent; and
- Some determination of what impact such a listing would have on generic drug manufactures that have already received final FDA approval would have to be made.

BMS respectfully submits that further judicial review of Mylan's purported action to delist the patent is unwarranted.

CONCLUSION

For the reasons set forth above, the petition for a writ of *certiorari* should be denied.

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Respectfully submitted,

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